

PATENT COOPERATION TREATY

PCT

REC'D 11 APR 2002

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

WIPO PCT

(PCT Article 36 and Rule 70)

10/049399

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| Applicant's or agent's file reference 14538A-53-1PC | FOR FURTHER ACTION See Notification of Transmittal of International Preliminary Examination Report (Form PCT/IPEA/416) | |
| International application No. PCT/US00/22226 | International filing date (day/month/year) 11 AUGUST 2000 | Priority date (day/month/year) 13 AUGUST 1999 |
| International Patent Classification (IPC) or national classification and IPC Please See Supplemental Sheet. | | |
| Applicant FRED HUTCHINSON CANCER RESEARCH CENTER | | |

1. This international preliminary examination report has been prepared by this International Preliminary Examining Authority and is transmitted to the applicant according to Article 36.

2. This REPORT consists of a total of 4 sheets.

☐ This report is also accompanied by ANNEXES, i.e., sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications made before this Authority. (see Rule 70.16 and Section 607 of the Administrative Instructions under the PCT).

These annexes consist of a total of 0 sheets.

3. This report contains indications relating to the following items:

- I ☒ Basis of the report
- II ☐ Priority
- III ☐ Non-establishment of report with regard to novelty, inventive step or industrial applicability
- IV ☐ Lack of unity of invention
- V ☒ Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability, citations and explanations supporting such statement
- VI ☐ Certain documents cited
- VII ☐ Certain defects in the international application
- VIII ☐ Certain observations on the international application

| | |
|--|---|
| Date of submission of the demand 07 MARCH 2001 | Date of completion of this report 28 FEBRUARY 2002 |
| Name and mailing address of the IPEA/US Commissioner of Patents and Trademarks Box PCT Washington, D.C. 20231 | Authorized officer <i>Holly Schnizer</i> HOLLY SCHNIZER |
| Facsimile No. (703) 305-3230 | Telephone No. (703) 305-0196 |

I. Basis of the report**1. With regard to the elements of the international application:***☒ the international application as originally filed☒ the description:

pages 1-38 , as originally filed
pages NONE , filed with the demand
pages NONE , filed with the letter of _____

☒ the claims:

pages 39-41 , as originally filed
pages NONE , as amended (together with any statement) under Article 19
pages NONE , filed with the demand
pages NONE , filed with the letter of _____

☒ the drawings:

pages 1-7 , as originally filed
pages NONE , filed with the demand
pages NONE , filed with the letter of _____

☒ the sequence listing part of the description:

pages 1-21 , as originally filed
pages NONE , filed with the demand
pages NONE , filed with the letter of _____

2. With regard to the language, all the elements marked above were available or furnished to this Authority in the language in which the international application was filed, unless otherwise indicated under this item.

These elements were available or furnished to this Authority in the following language _____ which is:

- ☐ the language of a translation furnished for the purposes of international search (under Rule 23.1(b)).
☐ the language of publication of the international application (under Rule 48.3(b)).
☐ the language of the translation furnished for the purposes of international preliminary examination (under Rules 55.2 and/or 55.3).

3. With regard to any nucleotide and/or amino acid sequence disclosed in the international application, the international preliminary examination was carried out on the basis of the sequence listing:

- ☒ contained in the international application in printed form.
☐ filed together with the international application in computer readable form.
☐ furnished subsequently to this Authority in written form.
☐ furnished subsequently to this Authority in computer readable form.
☐ The statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.
☐ The statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished.

4. ☒ The amendments have resulted in the cancellation of:

- ☒ the description, pages NONE
☒ the claims, Nos. NONE
☒ the drawings, sheets Fig. NONE

5. ☐ This report has been drawn as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).**

* Replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report since they do not contain amendments (Rules 70.16 and 70.17).

**Any replacement sheet containing such amendments must be referred to under item 1 and annexed to this report.

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No.

PCT/US00/22226

V. Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement**1. statement**

| | | | |
|-------------------------------|--------|--------------|-----|
| Novelty (N) | Claims | 1-6 and 9-15 | YES |
| | Claims | 7, 8 | NO |
| Inventive Step (IS) | Claims | 1-6 and 9-15 | YES |
| | Claims | 7, 8 | NO |
| Industrial Applicability (IA) | Claims | 1-15 | YES |
| | Claims | none | NO |

2. citations and explanations (Rule 70.7)

Claims 7 and 8 novelty under PCT Article 33(2) as being anticipated by HASEGAWA et al. (Database Geneseq 36 No. W69527).

HASEGAWA et al. disclose an N-terminal truncated factor VIII comprising an amino acid sequence identical to amino acids 2174-2326 of SEQ ID NO:1 of the present invention. Thus, the HASEGAWA et al. reference meets the limitations of the claims. Since Claims 7 and 8 lack novelty over the HASEGAWA et al. reference, it follows that these claims also lack an inventive step under PCT Article 33(3) as being obvious over HASEGAWA et al.

Claims 1-6 and 9-15 meet the criteria set out in PCT Article 33(2)-(3), because the prior art does not teach or fairly suggest of a crystal of the protein-ligand complex claimed or of a method of using the crystal.

Claims 1-15 meet the criteria set out in PCT Article 33(4) because the crystal of the protein-ligand complex claimed may be used industrially in structure-based drug design.

----- NEW CITATIONS -----

NONE

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Supplemental Box

(To be used when the space in any of the preceding boxes is not sufficient)

Continuation of: Boxes I - VIII

Sheet 10

CLASSIFICATION:

The International Patent Classification (IPC) and/or the National classification are as listed below:
IPC(7): C12P 21/04; C12N 9/00; C07K 1/00, 14/00; A61K 35/14 and US Cl.: 435/69.6, 183; 530/350, 383